Status of a Draft Standard for Personnel Screening Systems

ANSI/HPS Subcommittee N43.17 [1]

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Abstract

Security screening systems utilizing ionizing radiation have been installed by several institutions in this country and their number is growing. The Food and Drug Administration, which is the federal agency with jurisdiction over the radiation safety of these devices, does not currently have mandatory standards. This is a new technology applied to an old concept. Intentional exposure of people for non-medical purposes has been considered unacceptable in the latter half of the past century. There is a wide spectrum of opinions among the taskholders and little guidance for regulators and the industry. To address these issues the N43 Committee has appointed a subcommittee to draft a consensus standard. The subcommittee, consisting of regulators, manufacturers and users, has reached consensus on some of the main requirements of the standard. This talk will outline the requirements agreed upon and examine the ongoing discussions and proposals. Proposed dose limits will be presented. The rationale behind the proposed standard will be discussed in detail.

Introduction

A new imaging technology is rapidly gaining importance in screening applications for security and contraband. The image is obtained from a raster scan of an object using a narrow beam of ionizing radiation. Both backscattered and transmitted photons can be detected to form a computer image. This technology, which allows much lower doses than more conventional x-ray methods, is currently being used in the United States for inspecting cargo and for screening people. The HPS/ANSI Accredited Committee N43 has appointed a working group, N43.17, to draft a consensus standard for the application of this technology to the security screening of people. Currently, only backscatter systems are used for this purpose in this country. The standard under development provides guidelines specific to the radiation safety aspects of the design and operation of these systems. It does not include electrical safety guidelines or any other safety, performance or use considerations outside of the realm of radiation safety. The draft standard is titled "Radiation Safety for Personnel Security Screening Systems Utilizing Ionizing Radiation". The Subcommittee membership is shown in Table 1. The table of contents for the proposed standard is shown in Table 2.

[1] See Table 1 for list of members.

Member	Affiliation
Frank Cerra (Chair)	U.S. Food and Drug Administration
Martin Annis	AnnisTech
Edgar D. Bailey	California Department of Health Services and Conference of Radiation Program Directors
Larry Cothran/Terry Brayer	California Department of Corrections
Daniel Kassiday	U.S. Food and Drug Administration
Richard Whitman/Roy Lindquist/Pamela Zaresk	U.S. Customs Service
William Passetti	Florida Bureau of Radiation Control
Andy Kotowsky/Timothy Scroggins	Rapiscan Security Systems, Inc.
Gerald Smith/Richard Schueller	American Science and Engineering
Steve Smith	Spectrum San Diego, Inc.

Table 1. Subcommittee N43.17 members who contributed to the draft standard as of 1 October 2000.

Special Considerations

The devices, which are subject to this standard, are unique in that they intentionally expose people to ionizing radiation for non-medical purposes. The last time this has been done was in the 1950's when fluoroscopes were used in shoe stores for fitting shoes. Because of the unacceptable risks and high doses, this type of application was banned in most states. The current security scanners, however, deliver doses many orders of magnitude lower than the old shoe fluoroscopes and may have legitimate uses.

Existing radiation safety standards and regulations generally deal with either medical radiation exposure or consequential exposure to workers and the public from industrial or other applications. In the case of medical exposure, the prevalent consideration is the benefit to the patient as weighed against the risk associated with the radiation exposure. In the case of consequential exposure from human sources, the prevalent consideration is the minimization of a necessary exposure taking into account the economic and societal needs. The standard under development deals with exposures that are intentional rather than consequential but not medical. The associated doses are small and more resembling background doses than medical doses. However, the intentional nature of the exposures and the precedent that is being set demand special consideration. Hence the authors believe that the standard must take into equal consideration both factors: benefit versus risk and minimization of the dose. That is, it is not sufficient to keep the dose to standard protection levels, but there must also be a clear benefit. In this case the benefit is usually a more secure environment for those screened and/or those who come in contact with them. The present draft standard recognizes as legitimate only those uses that promote the preservation of human life and safety.

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Table 2. The table of contents of the draft standard as of 1 October 2000.

Dose Limits and Their Rationale

Dose to subjects being scanned

Various organizations have studied the biological effects of ionizing radiation exposure. The National Council on Radiation Protection (NCRP) has reviewed two independent studies, one by the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR 1988) and the other by the National Academy of Sciences/National Research Council, Committee on the Biological Effects of Ionizing Radiation (NAS/NRC 1990). Based on this review, the NCRP recommends that, for radiation protection purposes, a lifetime risk of fatal cancer of 5% per Sv

be used (NCRP Dec. 1993). Application of this risk estimate means that each 0.01 microSievert (1 microrem) of effective dose received would contribute 5×10^{-10}, or one chance in two billion, to an individual's risk of contracting a fatal cancer during his or her lifetime. These low-dose estimates assume a "linear, no-threshold" relationship between radiation exposure and health effects.

For frequent exposures to the general public, the NCRP recommends a yearly limit of 1.0 mSv (100 mrem) effective dose (NCRP Mar. 1993). The NCRP also recommends that any one site either not exceed 0.25 mSv (25 mrem) per year or ensure that exposed individuals not exceed 1.0 mSv (100 mrem) per year from all sources (excluding medical and natural sources). These recommendations are consistent with the recommendations by the International Commission on Radiological Protection (ICRP 1991) and were endorsed by the Health Physics Society (HPS 1993, 2000). Similar dose limits also appear in existing regulations of the Nuclear Regulatory Commission (10CFR20.1301) and the Environmental Protection Agency (40CFR190.10). Accordingly, the present draft standard requires that the operating facility ensure that no screened individual receive from the facility an effective dose in excess of 0.25 mSv (25 mrem) in any twelve-month period. In addition, a limit of 0.1 microSievert (10 microrem) per scan is imposed. There are several reasons for the latter limit. One is to make it virtually impossible to exceed the yearly limit. Assuming a scenario of 6 to 7 scans per day to be an extreme case, facilities should have no trouble identifying individuals with a potential for exceeding the yearly limit so that appropriate step may be taken. Another reason for the 0.1 microSievert limit is that present technology provides good imaging results within this limit. Preventing a higher than a necessary dose is consistent with the principle of ALARA (i.e. As Low As Reasonably Achievable).

Dose to operators

The main considerations in the Subcommittee's discussions of operator dose limits were the following: 1) because of the sensitivity of the systems, the radiation exposure rate in the surrounding environment must necessarily be kept very low. 2) It is desirable that the system operators be protected as general public rather than as radiation workers. 3) Operators have no need to be exposed to the primary x-ray beam and should never have access to the unshielded x-ray source. In view of these considerations an annual effective dose limit of 1 mSv (100 mrem) was set for the operators.

Dose to special groups

Various subgroups of the general population may be more susceptible to health effects than others. This includes pregnant and potentially pregnant women, children, infants, persons receiving radiation treatment for medical conditions, and so on. In some cases, the NCRP recommends lower limits on exposure to these special groups. For example, the NCRP recommends that the occupational limit for pregnant women be approximately eight times lower than for other workers. That is, 0.5 mSv per month (to the embryo or fetus) versus 50 mSv per year (NCRP Mar. 1993). However, these reduced limits for special groups are only made for radiation doses that are far in excess of what is covered by this standard. The reduced monthly limit on occupational exposure to a pregnant woman is twice the yearly limit under this standard and corresponds to approximately 5,000 security examinations per month. The NCRP makes no distinction between members of the population in its recommendations on exposure for the

general public. Correspondingly, the Subcommittee sees no need to distinguish between members of the population being scanned by the products operating under this standard.

Dose to bystanders

It is conceivable that in some of the installations people may wander into the path of the primary beam behind the person being scanned. To prevent this, the draft standard requires a restricted area to be established around the personnel security screening system where bystanders are prohibited during the operation of the device. Radiation doses outside of this restricted area are not to exceed 0.02 mSv (2 mrem) in any one-hour period.

ALARA considerations

Under recommendations of the NCRP, workers in radiation areas can receive up to 0.05 Sv (5 rem) per year. Likewise, NCRP recommends that members of the general public, including special groups such as pregnant women and children, receive less than 1 mSv (0.1 rem) per year. Both these levels are subject to the radiation safety principle of ALARA. That is, even though these exposures may be acceptable, they must be kept As Low As Reasonably Achievable, while taking into account the benefit derived from the exposure. As an exposure is made smaller, the risk from the exposure is also reduced correspondingly. When the exposure is reduced beyond a certain point it becomes indistinguishable from variations in the natural background. The NCRP defines a category for extremely low radiation exposures called the Negligible Individual Dose (NID), and sets its value at 0.01 mSv (1 mrem) per year (NCRP Mar. 1993). At radiation exposures below the NID, efforts to reduce the dose further are not warranted.

These recommendations can be applied to the 0.1 microSievert (10 microrem) maximum dose per scan produced by systems operating under this standard. By direct calculation, an individual screened less than 100 times per year would receive a radiation exposure within the NID. Likewise, an individual screened up to 10,000 times per year would still be within the recommended dose limit for members of the general public (assuming the individual did not received radiation exposure from any other another source). However, the use of radiation exposure in personnel security screening is a unique and specific application. Accordingly, it is the intent of the Subcommittee to help further define the acceptable uses of the technology, and to interpret the principles of ALARA and NID in this particular context. In particular, regardless of the dose level, products operating under the standard should only be used in the legitimate search for concealed weapons and contraband, plus related activities, such as training and service. Use of these systems for unnecessary or frivolous activities is contrary to the recommendations of the standard, and the intended use of the applicable products.

Consistent with the principles of ALARA and NID, the number of examinations an individual receives per year can be divided into two general categories. In applications where the subject is likely to receive less than 0.01 mSv (1 mrem) per year, procedures for conducting scans can generally be based on the necessity of the scan, without explicit consideration of the radiation dose involved. That is, when subjects are examined less than about 100 times per year the primary concern is that the product not be used for any unnecessary or frivolous activity. In applications where significantly more frequent examinations are conducted, reasonable efforts should be made to reduce the number of scans, taking into account the nature of the application. This does not mean that 0.01 mSv (1 mrem) per year is a safety limit or a sharp division between

two regulatory categories. Rather, it is meant to provide users of the products a general guideline regarding when efforts should be expended to reduce the number of examinations taking place.

Other Radiation Safety Requirements

Design and manufacturer requirements

In addition to the above dose limits the draft standard includes requirements for shielding, controls, indicators and safety interlocks. The shielding requirement limits the dose rate to a maximum of 2.5 microSievert hr^{-1} (0.25 mrem hr^{-1}) at any point 30 cm from any external surface of the device, excluding the beam exit surface but including any surface intended as a primary beam stop. A key switch is required to turn the power on, the key being captured when in a position allowing a beam-on condition. Indicators, clearly visible to both operator and subject, are required to show when a scan is in progress. For systems that normally keep high voltage applied to the x-ray tube at times other than during a scan, a lighted "x-ray on" indicator at the control console is also required. Safety interlocks are required for access panels to the x-ray source and for terminating x-ray production in case of a malfunction, such as stoppage of beam motion. Any residual exposure following such a malfunction is limited to a dose-area-product of 0.25 microSievert cm^2 (approx. 25 microrem ft^2), i.e. 0.0025 microSievert averaged over a 1000 cm^2 area.

The draft standard requires the manufacturer to provide the following information to the user facility: warnings of life threatening dangers (such as unauthorized modification of the product); requirements for state licensing; operational procedures needed to use the product safely; and preventive maintenance requirements for safe operation.

Operating requirements

The requirements for the operating facility include: designation of the individual accountable; installation, operation and maintenance schedule consistent with manufacturer's recommendations; minimum operator training requirements; annual radiation surveys; records to be kept; and information to be provided to individuals screened.

Operator training is to cover as a minimum the following topics: basic radiation safety, operating procedures, possible safety hazards (e.g. from unauthorized disassembly), information to be provided to the subject, physical security and restricted areas. It is recommended that proficiency be demonstrated at the conclusion of training. In addition, annual refresher courses are required.

The required radiation surveys must verify subject dose, radiation leakage, restricted area, and any other parameter specified by the manufacturer.

The draft standard requires the operating facility to maintain an operating procedures manual and the following records: operator training and qualifications; records of maintenance and repairs; records of radiation surveys; the name and qualifications of the responsible individual; records or other evidence to show that the prescribed dose limits are being met; and estimated workload (number of scans).

Information to be supplied to each person being scanned includes the radiation dose, the associated risk (including a comparative example) and the status of conformance of the system with applicable standards and regulations. It is recommended that the individual be also informed on how to obtain more information.

Conclusion

The ANSI/HPS Subcommittee N43.17 has worked to formulate radiation safety guidelines for the manufacture and operation of personnel security screening systems. This paper summarizes the progress until October 2000. It is anticipated that a final draft of the consensus standard will be submitted to the N43 Main Committee shortly following this HPS 2001 Midyear Topical Meeting. It is hoped that the standard will serve as guidance for the manufacture, operation and regulation of these novel products. For this to be a successful standard it must appeal to all the interested parties. Individuals or organizations who have comments or concerns are encouraged to submit their views either by contacting a task group member or, more formally, through the ANSI comment process.

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